REMARKS

Claims 1-8 remain in the application for consideration by the Examiner. Applicants respectfully request reconsideration and allowance of these claims for at least the following reasons.

In the foregoing Listing of Claims, Applicants remove the word "layer" from lines 10, 14, and 15 of claim 1. In the rejection of Applicants' claims under 35 U.S.C. §112, second paragraph, the Office Action suggested deleting the word "layer" from lines 10, 14, and 15 of claim 1 to remove alleged indefiniteness in the claim. Since Applicants' amend claim 1 in the manner requested in the Office Action, Applicants respectfully submit that claim 1 and the claims that depend thereon particularly point out and distinctly claim the subject matter which Applicants regard as the invention within the meaning of 35 U.S.C. §112, second paragraph. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of Applicants' claims under the second paragraph of 35 U.S.C. §112.

The Office Action provisionally rejected claims 1-4 on the grounds of nonstatutory double patenting over claims 17-21 of copending Application No. 10/690,811. Applicants submit herewith an appropriate Terminal Disclaimer and the appropriate government fee therefor. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the double patenting rejection.

On pages 3-8, the Office Action rejected claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over Nogami (EP 1391212, which is available under §102(b) either itself or as a translation of WO document 02/087622, and is equivalent to US 2004/0137040 and its correction US 2008/0254102). The Examiner stated that Nogami teaches, as a whole, a method for

producing a multi-layered pharmaceutical composition by joining two drug containing intermediates via heat fusion. Applicants respectfully submit that the teachings of Nogami do not disclose or suggest the inventions defined in present claims 1-8 within the meaning of 35 U.S.C. §103 for the reasons set forth in the Amendment filed on January 12, 2009, which are incorporated herein by reference, and for at least the following reasons.

An advantage or property or an unexpected advantage or property of the presently claimed invention is a significant reduction in the heating time required to form the drug-containing layer. This advantage or property or unexpected advantage or property of the presently claimed invention is not contemplated or suggested by Nogami. Attention is respectfully directed to Exhibit A attached to the end of this Amendment. Applicant respectfully submits that the showing in the attached Exhibit A demonstrates the surprising and unexpected advantages of the presently claimed invention.

Attached Exhibit A contains data, discussions, and graphical representations based on pages 29-34 of Applicants' specification. Exhibit A demonstrates that the heating time required to form the drug-containing layer by the method of the present claims is significantly and unexpectedly shorter than the heating time required by other methods, such as those represented by Comparative Examples 1 and 2. On page 5, the Office Action stated that Nogami teaches forming an intermediate comprising a water-swellable gel-forming layer, a drug-containing layer, and an adhesive layer in that order on a support. The Office Action continued that Nogami teaches these steps are repeated to form another intermediate adhesive layer and the two intermediates are then heat-fused to one another. As shown in the attached Exhibit A, Comparative Example 3 of the present application includes the steps of using an adhesive layer

forming liquid to form an adhesive layer (dry) for the intermediate and then joining two intermediates, as allegedly taught by Nogami according to the Office Action. As shown on page 4 of Exhibit A, the examples according to the presently claimed invention (Examples 1-3) have a drug heating time (in seconds) of 602, whereas Comparative Example 3 has a drug heating time of 782 seconds. Accordingly, the presently claimed invention has a 30% ((782-602)/602) reduced drug heating time; when compared to Comparative Example 3, which allegedly corresponds to the method proposed by Nogami.

Applicant respectfully submits that the showing of unexpected properties as shown in the attached Exhibit A concerning the reduction in drug heating time by 30% for the presently claimed invention demonstrates significant and unexpectedly improved results. Therefore, Applicants respectfully submit that the showing in Exhibit A, which represents discussions in and data from the present application are sufficient to establish unexpected results and thereby distinguish the presently claimed invention from the teachings of Nogami. *In re Soni*, 54 F.3d 746, 34 USPQ2d 1664 (Fed. Cir. 1995).

At least for the foregoing reasons, Applicants respectfully submit that the presently claimed invention is patently distinguishable from Nogami within the meaning of 35 U.S.C. §103. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-8 over the teachings of Nogami.

Applicants believe that the foregoing is a complete and proper response to the Office Action mailed April 20, 2009. While it is believed that all claims in this application are in condition for allowance, if the Examiner has any comments or questions, Applicants invite the

Examiner to telephone the undersigned at the below listed number to resolve any outstanding issues.

In the event this paper is not timely filed, Applicants hereby petition for an appropriate extension of time. The Commissioner is hereby authorized to charge the fee therefor, as well as any other fees which become due, to our Deposit Account No. 50-1147.

Respectfully submitted,

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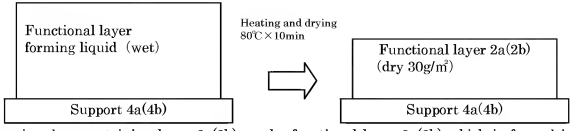
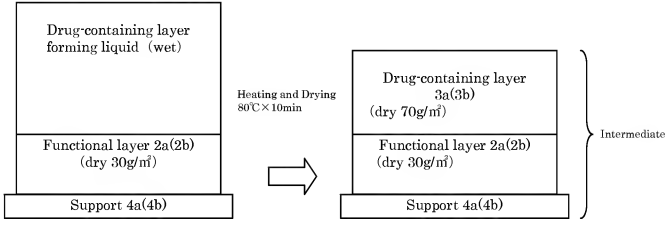
Attachments:
1. Exhibit A
2. Terminal Disclaimer, and
3. Terminal Disclaimer Fee.

[Producing method of Examples 1～3]

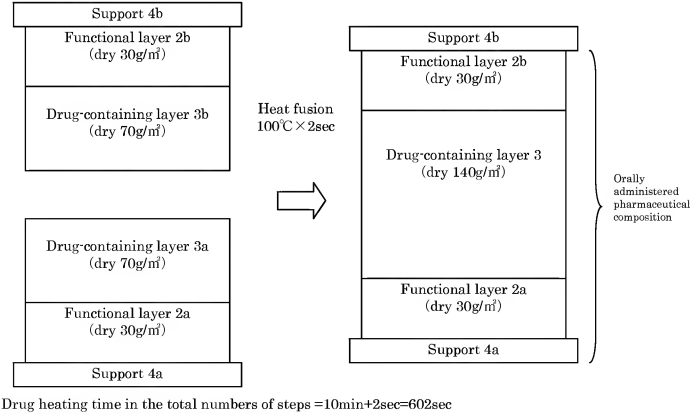
1. Forming functional layer 2a(2b) on support 4a(4b)



2. Forming drug-containing layer 3a(3b) on the functional layer 2a(2b) which is formed in above-mentioned 1.



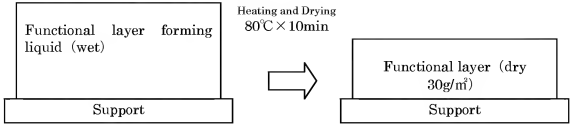
3. Step of heat fusion



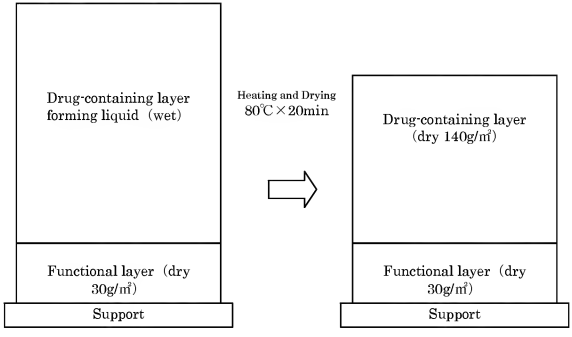
※ Drug heating time in the total numbers of steps =10min+2sec=602sec
(The description of Table2 is not correct.)

[Producing method of Comparative Example 1]

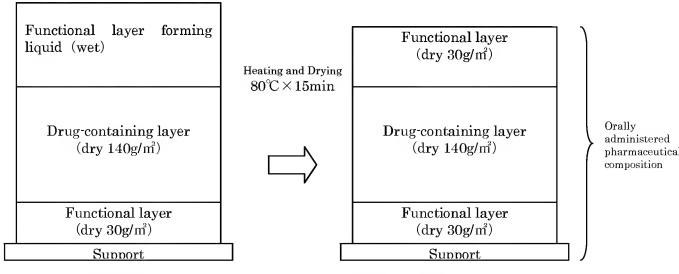
1. Forming functional layer on support



2. Forming drug-containing layer on the functional layer which is formed in above-mentioned 1.



3. Forming functional layer on the drug-containing layer which is formed in above-mentioned 2.



※ Drug heating time in the total numbers of steps =20min+15min=2100sec

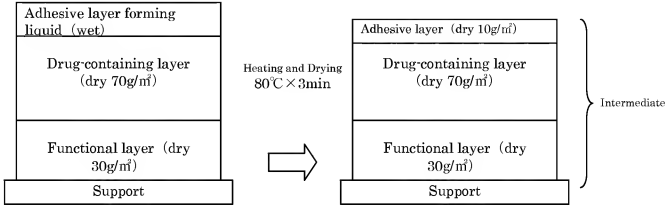
※ The reason step 3 takes time than step 1 is that: the solvent evaporates once being absorbed into the drug-containing layer, and therefore step 3 takes time than step 1 to dry up the solvent.

[Producing method of Comparative Example 2]

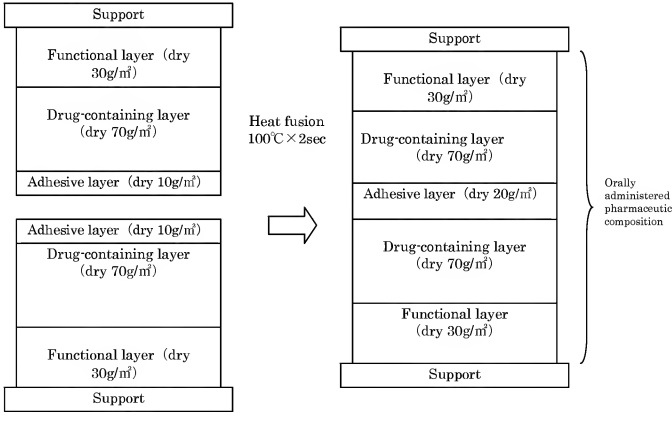
1. Forming functional layer on support
   Same with the Example.

2. Forming drug-containing layer on the functional layer which is formed in above-mentioned 1.
   Same with the Example.

3. Forming adhesive layer on the drug-containing layer which is formed in above-mentioned 2.



4. Step of heat fusion



※ Drug heating time in the total numbers of steps=10min+3min+2sec=782sec.[1]

[1] This corrects the description for Comparative Example 2 (the second Comparative Example 1) in Table 2 on page 32 of the application.

Conclusion:

In forming orally administered pharmaceutical compositions which contain the same 140g/m^{2}of drug-containing layers, comparing the drug heating time, there is an effect on minimizing the drug heating time by the use of the producing method of the present invention, as shown in the below table.

	Drug heating time (secs) in total steps
Examples 1~3	602
Comp.Ex.1	2100
Comp.Ex.2	782